Control Number: 14-009

JUSTIFICATION AND APPROVAL
FOR OTHER THAN FULL AND OPEN COMPETITION

1. Contracting Activity: Department of Veterans Affairs
Office of Acquisition Operations
Technology Acquisition Center
260 Industrial Way West
Eatontown, New Jersey 07724

2. Description of Action: The proposed action is for a 12-month Firm-Fixed-Price (FFP) contract with two 12-month option periods and optional tasks for the renewal of a comprehensive pharmacy drug database and associated decision support tools from First Databank (FDB). This effort will provide enterprise wide pharmacy support for the Department of Veterans Affairs (VA), Veterans Health Administration (VHA), Pharmacy Service, and Indian Health Services (IHS).

3. Description of the Supplies or Services: FDB's proprietary code has been integrated into the software code of the current VA Computerized Patient Record System (CPRS)/Veterans Health Information Systems and Technology Architecture (VistA) operating system. CPRS/VistA is the Electronic Medical Record (EMR) used to provide care to Veterans. The current system provides a mechanism to cross check several critical factors in relation to patient pharmaceutical safety, such as Patient Medication Information Sheets (PMIS), auxiliary warning labels, drug-drug interactions, duplicate drug order checks and maximum single dose checks. Unless VA has a source for this type of information, VA cannot meet its obligations to effectively administer medication to Veterans. Order checks and other information such as PMIS information also must be incorporated into the ordering and prescription filling process. Without an integrated system, order checks are of no value because research indicates that ordering information is only useful within the ordering process when validated in real time. Therefore, VA has embarked on several major projects to ensure that medication order checks and associated decision support tools be incorporated into ordering and prescription filling processes. These projects resulted in the following systems: Medication Order Check Healthcare Application (MOCHA), Pharmacy Product System (PPS) and the Pharmacy Enterprise Customization System (PECS). In addition, other VA systems including the Consolidated Mail Outpatient Pharmacy and the Clinical Data Repository/Health Data Repository system have been modified to use FDB data and associated application programming interfaces (APIs). FDB's National Drug Code (NDC) identifier and pricing information is used to validate VA's class of products and to verify that the contractual prices for medications are at or below the open market pricing. The development of these systems has been time consuming and expensive, exceeding five years at a cost of more than $10 million.

4. Statutory Authority: The statutory permitting other than full and open competition is 41 U.S.C 3304(a)(1) as implemented by the Federal Acquisition Regulation (FAR) Subpart 6.302-1 entitled, “Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements."

5. Rationale Supporting Use of Authority Cited Above: This effort is proposed to be awarded to FDB, 500 E. 96th Street, Suite 500, Indianapolis, Indiana, 46240. VA must continue to support mission critical services such as drug to drug interactions, duplicate therapy, dosing, patient medication information sheets, and VA-Department of Defense (DoD) interoperability to ensure patient safety between healthcare systems. Currently, there are multiple other VA applications and servers that utilize FDB as a key part of their software in performing the necessary cross checks to ensure patient pharmaceutical safety. The three main systems, which are fully deployed, nationally operated systems are PECS, MOCHA, and PPS. These systems utilize only FDB to perform the necessary drug to drug interactions checks, duplicate therapy checks, dosing, patient medication information sheets (PMIS), and provide VA-DoD interoperability between healthcare systems.

Each of these three production systems have servers and software which are fully deployed and are operating in direct support of pharmacists at all VA facilities. These applications have been specifically developed for use with the proprietary FDB software. If VA is no longer able to use FDB, the deployed versions of these applications would be rendered useless. Each of these production systems has undergone extensive development through creation of thousands of lines of code in order for them to adequately use FDB’s proprietary product ensuring cross checking is performed for several critical factors in relation to patient safety, such as PMIS, auxiliary warning labels, drug-drug interactions, duplicate drug order checks and maximum single dose checks. Furthermore, while the PECS, MOCHA, and PPS systems have all been deployed and coded to interact solely with FDB, there are also planned versions with enhancements currently under development and testing as well. If FDB is suddenly replaced with a new tool, many of those versions that are already developed, or are partially developed and are now undergoing testing, will be rendered useless and have to be recoded,preventing the latest in technological advances from being deployed rapidly in support of Veterans’ healthcare. It is anticipated that it would take 2.5 years to recode these systems based on the timeline to originally code the systems. In addition to updating systems and interfaces, previous data and information used as inputs that are dependent on FDB data structures would also have to be analyzed and mapped to whatever data structure a new COTS solution would use to allow order check histories, and ensure data generated under the old tool matches and maps to data under the new tool. The introduction of another solution to perform this vital cross checking process would require every system that utilizes it to be created and/or recoded, retested, recertified for security accreditation, and redeployed. If VA does not continue to utilize FDB, each of these production systems will be

rendered useless and would shut down, or not function properly until a new solution could be recoded, retested, and redeployed. This would leave pharmacists with no tools to conduct order checks to prevent patient safety issues and harmful drug interactions during any transition period, which would have a severe negative impact on Veterans' healthcare. In addition, it is estimated that switching current CPRS/VistA systems to a new vendor, other than FDB would exceed $4 million and take approximately 2.5 years to complete.

6. Efforts to Obtain Competition: Market research was conducted, the details of which are in the market research section of this document in paragraph 8 below. The market research conducted did not yield any potential sources, other than FDB, who could meet all of the Government's requirements. There is no competition anticipated for this acquisition. Additionally, the proposed action will be synopsized on the Federal Business Opportunities Page (FedBizOpps) in accordance with FAR Part 5.

7. Actions to Increase Competition*:* In order to remove or overcome barriers to competition in future acquisitions for this requirement, the agency will work with the program office to perform additional market research so that other solutions can be considered.

8. Market Research: The Government's technical experts conducted market research by posting a draft Performance Work Statement of the Government's needs in Request for Information (RFI) number VA118-14-Q-0042 which was posted on FedBizOpps in November 2013. In the RFI, the Government requested capability statements from vendors that to demonstrate their current ability to provide a comprehensive pharmacy drug database and associated decision support tools. Two responses were received. One response was received from the incumbent contractor, FDB, and one response was received from Wolters Kluwer Health, Inc. (WKH).

A review of the RFI responses by VA technical experts found only FDB to be technically capable to meet the Government's requirements. There were several technical reasons for this finding. Both FDB and WKH are programs that are dependent on other technologies in order to operate effectively. WKH does not meet VA's requirements, specifically the aforementioned interoperability requirements. In order for VA to utilize the WKH system, the software code for CPRS/VistA, PECS, MOCHA, and PPS systems would have to be recoded. In addition, WKH poses other technical challenges. Since WKH uses a unique proprietary identification system, VA would need to reassign all products currently in VA's pharmacy product system to align with the WKH proprietary identification system. The current clinical decision support system is based on proprietary FDB API and is incompatible with the WKH proprietary APIs. VA has highly customized the current FDB drug-drug interaction data to meet its needs. Currently 114,456 out of 430,596 (27%) validated drug pairs have been customized. Using a new solution would require that this work be redone. VA

currently uses a combination of Cachae and Oracle servers. It is unknown if the WKH system would work in this unique server environment. Patient Medication Information Sheets are currently hard coded into VistA files. These files are based on a FDB customized update process. The process and base files would need to be replaced to utilize a different solution. Using WKH would pose both unacceptable technical risk and patient risk. If VA does not continue to utilize FDB, each of the production systems referenced above will be rendered useless and would shut down, or not function properly until a new solution could be recoded, retested, and redeployed. This would leave pharmacists with no tools to conduct order checks to prevent patient safety issues and harmful drug interactions during any transition period, which would have a severe negative impact upon Veterans' healthcare. The Government contacted WKH in December 2013 to advise them of the Government's assessment that WKH's product cannot meet VA's needs. Based on this market research, the Government's technical experts have determined that only FDB can meet all of VA's needs.

9. Other Facts: A contract with FDB for database and decision support tools was awarded in 2006 for the Office of Pharmacy Reengineering Project (PRE) utilizing best value procedures. The award was based on the quality of the database content and API. The award was based on the best overall proposal that was determined to be the most beneficial to the Government. It was determined through the evaluation process that FDB provided the best value to the Government. The PRE project has been utilizing FDB to enhance order checks. These enhanced order checks have been used to improve patient safety. These order checks include drug-drug interactions, duplicate therapy and dosing. These dosing checks are also used interdepartmentally with DoD. The continuation of these safety checks are essential to VHA and IHS in order to carry on the mission of providing the best healthcare for Veterans. Without these order checks the CPRS/VistA operating system will also not be in compliance with accreditation systems such as the Joint Commission. Order checks are also required to obtain certification by the Office of the National Coordinator for Health Information Technology for the 2014 edition criterion (Meaningful Use).